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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,454	09/17/2003	Mark L. Jenson	760-68 RCE II	4333

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EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,454	JENSON, MARK L.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,19,20,22,26,27 and 48-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,19,20,22,26,27 and 48-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The amendment filed 5/22/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the surface formed by liner 14 is a smooth surface while the surface formed by liner 16 is an uneven surface. If the liners 14, 16 are joined at a location between the interior surface 18 and the exterior surface 20, both surfaces 18, 20 would be uneven. If the liners 14, 16 are joined at a location that is coextensive with the exterior surface 20 of the stent, the exterior surface 20 would be smooth and the interior surface 18 would be uneven.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 50, and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 27 contains the new matter cited in the amended specification filed 5/22/2009, as described above. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13, 14, 48, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. (US Pat. No. 6,149,681) in view of DiMatteo et al. (US Pat. No. 6,440,164). Houser et al. discloses the following of the claimed invention as shown in Figure 42: a composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: a first polymeric liner (inner element 246); a second polymeric liner (outer element 246); an intermediate structural member or elongate stent (258) interposed between said first and said second polymeric liners, said intermediate structural member being defined by solid segments and openings therebetween such that the first liner is bonded to the second liner through said openings to form at least one pocket adjacent to said solid segments, said pocket being defined by said first and second liners, their area of direct bonding, and said solid segments; and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said intermediate structural member (col. 3, lines 41-52). Houser et al. further discloses the limitations of claims 13-15 in col. 7, lines 50-58. With respect to the choice of a trapezoidal cross-section, applicant's specification fails to establish a showing of criticality for the particular design. Therefor, it would have been an obvious matter of design choice to use a solid segment with a trapezoidal cross-section as such modification would have involved a

mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art.

Houser et al. does not disclose the first liner being bioabsorbable and the second liner being made from ePTFE. DiMatteo et al. teaches an implantable stent and prosthetic valve that includes a bioabsorbable liner and a liner made from ePTFE in col. 10, lines 10-38, col. 11, lines 36-53, and col. 13, lines 50-65 for the purpose of utilizing the materials' biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the liners of Houser et al. to be constructed from ePTFE and a bioabsorbable material in order to utilize the materials' biocompatibility.

Houser et al. and DiMatteo et al. disclose the claimed invention except for the internodal distance of the ePTFE material. It would have been obvious tone having ordinary skill in the art at the time the invention was made to use an ePTFE material with an internodal distance of about 5 to 10 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al., further in view of Rudakov et al. (US Pat. No. 6,451,050). Houser et al., as modified by DiMatteo et al., discloses the invention substantially as claimed, however, they do not teach encapsulating a bioactive agent in a polymeric matrix. Rudakov et al. teaches a stent where the bioactive agent is encapsulated in a polymeric matrix in col. 4, lines 40-50 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious

to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al. and Rudakov et al., as shown in claim 11, further in view of Helmus et al. (US Pub. No. 2002/0032477). Houser et al., as modified by DiMatteo et al. and Rudakov et al., discloses the invention substantially as claimed, however, they do not teach constructing the polymeric matrix holding the bioactive agent of microparticles. Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix in paragraph 0048 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claims 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al., further in view of Golds et al. (US Pat. No. 6,001,125). Houser et al., as modified by DiMatteo et al., discloses the invention substantially as claimed, however, they do not teach using porous ePTFE to construct the device. Golds et al. teaches a vascular graft constructed from porous ePTFE in columns 3 and 4 for the purpose of utilizing the material's enhanced radial strength of the less porous area and the enhanced cell endothelialization associated with the more porous area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use porous ePTFE in order to utilize the material's radial strength and cell endothelialization.

Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al., further in view of Rhodes (US Pat. No. 5,665,117). Houser et

al., as modified by DiMatteo et al., discloses the invention substantially as claimed, however, they do not teach using stainless steel or tantalum to construct the device. Rhodes teaches a biological prosthesis that uses stainless steel or tantalum to construct the device in col. 6, lines 8-30 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use stainless steel or tantalum to construct the device in order to utilize the material's biocompatibility.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al., as modified by DiMatteo et al., in view of Yang (US Pub. No. 2002/0062147). Houser et al., as modified by DiMatteo et al., discloses the invention substantially as claimed, however, they do not teach using a gel to contain the bioactive agent. Yang teaches a biological prosthesis that uses a gel to contain the biological agent in paragraph 0073 for the purpose of retaining the drug in the device for a longer period of time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a gel to contain the bioactive agent in order to retain the drug in the device for a longer period of time.

Response to Arguments

Applicant's arguments with respect to claims 1-14, 19, 20, 22, 26, 27, and 48-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774